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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/770,259

02/02/2004

Kikuzo Okada

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9594

7590

09/23/2008

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

09/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/770,259	<b>Applicant(s)</b> OKADA ET AL.	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 18 and 20-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of RCE, claims and response dated 6-20-08.

Claim 19 deleted. Claims 1-18 and 20-32 are pending. Claims 1-4, 17-18 and 20-32 are under consideration for examination.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-20-08 has been entered.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-4, 17-18 and 20-32 have been considered but are moot in view of the new ground(s) of rejection.

The following new rejections are applied:

#### ***Claim Rejections - 35 USC § 112***

1. Claims 1, 17, 20-25 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention. Instant claims recite keratin and also protein in addition to the reducing agent. A review of the instant specification does not provide any description of proteins other than keratin that may be added to the composition. Applicants have not provided any description what types of proteins could possibly be included in the instant composition and hence the term proteins lack written description.

***Claim Rejections - 35 USC § 102***

2. Claims 1, 2, 4, 26, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4121904 to Schamper.

Schamper teaches depilatory compositions for treating keratin comprising sodium thioglycolate and calcium thioglycolate and the composition is in the form of a cream or paste (abstract, col. 50, L 22-39 and table in col.5). The amount of thioglycolate in the composition is between 2% to 8% (see col. 3, L 40-50), which falls within the claimed range. For the claims 4 and 29, the limitation “is subjected to a deodorizing treatment” denotes a product by process limitation, in which the process steps do not carry any patentable weight in a composition claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a

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different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The limitation "for correcting a deformed nail or modifying the structure of a nail modification" of the instant claims denotes future intended use and only requires that the composition is capable of treating nails. Accordingly, Schamper anticipates instant claims.

3. Claims 1-4 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,982,749 to Baker et al (Baker).

Baker teaches a hair relaxing composition comprising ammonium thioglycolate in the form of a gel, where in the composition has 5% to 10% of ammonium thioglycolate (see col. 3, l 1-15 and claim 10). The limitation "for correcting a deformed nail or modifying the structure of a nail modification" and "is subjected to a deodorizing treatment" denotes a product by process limitation", see the explanation above. Thus, Baker anticipates instant claims.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 18, 26-29 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/57845 (WO) in view of JP407285830 (JP).

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WO discloses a nail softening compositions comprising at least one sulfur containing compound in an effective amount to soften the tissue and also an antimycotic agent. According to WO, the effective amount ranges between 0.15 to 40% (page 6, L 20-24) and the sulfur containing compounds include cysteine and thioglycolic acid and its ammonium salts (page 7, figure 5). WO teaches the composition in the form of gel, creams etc (page 9, L 1-3) and for antifungal agents, see page 10, L 16-25. The limitation "for correcting a deformed nail or modifying the structure of a nail modification" and the process of step of claim 26 have been addressed above.

WO fails to exemplify or teach a specific composition in the form of a paste, cream or gel. However, WO suggests that the composition may in a gel or a cream form and accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the nail softening composition of WO containing sulfur containing composition and a antimycotic agent in the form of a gel or a cream and still achieve the same effect in softening the nails or a horny layer.

5. Claims 17, 20-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/57845 (WO) as applied to claims 1-4, 18, 19, 26-29 and 31-32 above, and further in view of US 6200553 to Busch Jr., or in view of JP407285830 (JP, abstract only).

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WO lacks the second component i.e., carotene, protein, keratin or calcium in their composition.

Busch Jr. discloses finger nail compositions comprising calcium and fluoride for remineralization of finger nails. Busch teaches that the fingernail contains the least amount of natural calcium of the group consisting of bone, teeth and fingernails. While the calcium content of teeth and bone exceed 20% in various forms; the calcium content of fingernails is about 0.1% (introduction). Busch teaches that the calcium compounds may be applied in the form of a cosmetic cream (examples).

JP teaches a nail care composition to be applied to the nails is in the form of an organic solution or dispersion with organic medium, and contains 0.01-0.5 wt % of phytane triol acting as a nail regenerator or film-forming agent capable of coating the nails there with, and in addition, may contain 0.01-5 wt % of such activator(s) as to enable the nails to be treated, protected, fed with nutrients, hardened, regenerated, and/or fed with moisture. The additional components are selected from N- butylformaldehyde, D-panthenol, vitamins and their derivatives, keratin derivatives, cysteine, chitosan derivatives, ceramides, biotin, microelements, glycerol, protein hydrolysates, phospholipids, antifungal agents and antibacterial agents. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include the calcium compounds of Busch Jr. in the composition of WO containing sulfur compounds and antimycotic agents because while WO teaches treating nails for fungal

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infections, Busch teaches nail strengthening with calcium, thus constituting analogous art. A skilled artisan would have expected nail treatment for fungal infections and also strengthening of the nails from the combination of WO and Busch.

Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include vitamins, proteins or keratin of JP in the nail care composition of WO because JP teaches that the keratin, cysteine, proteins and vitamins provide treatment, protection and/or regeneration of nails. A skilled artisan would have expected an additional protection or regeneration with the components of JP in the composition of WO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner,  
Art Unit 1611  
September 18, 2008